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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

CLARENCE CLARK and ATRAMEAS CLARK, Individually and as Next Friends and Natural Guardians of KORTNEE CLARK, a Minor; V. CIBA VISION CORPORATION, NOVARTIS PHARMACEUTICALS, CORP. and YOON KYUNG LEE and MEE RAE LEE, d/b/a BEAUTY MAX.	CIVIL ACTION NO.

DEFENDANTS', CIBA VISION CORPORATION'S AND NOVARTIS PHARMACEUTICALS CORP.'S, NOTICE OF REMOVAL

Defendants, CIBA VISION CORPORATION and NOVARTIS PHARMACEUTICALS CORP. jointly file this notice of removal under 28 U.S.C. §1446(a), attaching the following documents in accordance with Local Rule 81:

- pursuant to LR 81.1, executed process is attached as **Exhibit A;**
- pursuant to LR 81.2, pleadings asserting causes of actions are attached as **Exhibit B**;
- pursuant to LR 81.2, answers to pleadings are attached as **Exhibit C**;
- pursuant to LR 81.3, all orders signed by the state judge are attached as **Exhibit D**;
- pursuant to LR 81.4, the docket sheet is attached as **Exhibit E**;
- pursuant to LR 81.5, an index of matters being filed is attached as **Exhibit F**; and
- pursuant to LR 81.6, a list of all counsel of record is attached as **Exhibit G**.

I. JURISDICTION

1. This court has jurisdiction over this matter according to 28 U.S.C. § 1331, 28 U.S.C. § 1441(c), U.S. Const. art. VI., and 21 U.S.C. § 360c *et seq.*, for the reasons explained in Part IV below.

II. VENUE

2. Venue is proper in this district under 28 U.S.C. §1441(a) because the state court where the suit has been pending is located in this district.

III. INTRODUCTION

3. The plaintiffs are Clarence Clark, Atrameas Clark, and Korntee Clark ("*Plaintiffs*"). The defendants are CIBA VISION CORPORATION ("*CIBA*"); NOVARTIS PHARMACEUTIALS CORP. ("*Novartis*"); and Yoon Kyung Lee and Mee Rae Lee, d/b/a BEAUTY MAX (collectively, the "*Beauty Max Defendnats*").

4. On June 8, 2010, Plaintiffs filed *Plaintiffs' First Amended Original Petition and Request for Disclosure* (*see* **Exhibit B**, pp. 17-29, hereinafter, the "*Petition*".) In the Petition, Plaintiffs allege CIBA and Novartis are liable for negligence and for strict liability under the Texas Civil Practice and Remedies Code and the common law of the State of Texas for allegedly causing injuries allegedly sustained from the use of a product allegedly designed, manufactured, marketed, and distributed by CIBA and Novartis. (*See* **Exhibit B**, pp. 23-25, *Petition*, pt. VII.) Plaintiffs also allege Beauty Max defendants are liable for non-manufacturing seller liability under the Texas Civil Practice and Remedies Code.

5. The Petition states that all claims against CIBA and Novartis arise from the design, manufacture, marketing, and distribution of a "subject product." (*See* **Exhibit B**, pp. 21, *Petition*, pt. V.) The Petition defines "subject product" to mean "the 'Fresh Look' non-prescription color contact lenses . . . originally designed, manufacturer [sic], marketed, warranted, and sold by . . . Ciba." (*See* **Exhibit B**, pp. 21, *Petition*, pt. V.)

6. CIBA does not design, manufacture, market, warrant, or sell any "non-prescription" contact lens. (**Exhibit H**, Aff. of J. O'Donnell, 2:19-23; 3:1.)

7. Although none of CIBA's products are named or marketed as "Fresh Look," CIBA has as many as twelve distinct product lines bearing the FreshLook® mark. (**Exhibit H**, Aff. of J. O'Donnell, 3:3-5.) All product lines bearing the FreshLook® mark are soft hydrophilic contact lenses intended to be worn directly against the cornea and adjacent limbal and scieral areas of the eye to correct vision conditions and to enhance or alter the apparent color of the eye. (**Exhibit H**, Aff. of J. O'Donnell, 3:5-9.) Some of the product lines bearing the FreshLook® mark contain products intended for daily wear only. (**Exhibit H**, Aff. of J. O'Donnell, 3:10-11.) These daily wear only lenses are products classified as Class II medical devices requiring premarket notification under § 510(k) of the Federal Food, Drug, and Cosmetic Act (the "*FDCA*"). *See* 21 C.F.R. § 886.5925(b)(1) (classifying daily-wear only lenses as Class II); *see also* 21 U.S.C. § 513(a)(1)(B) (requiring premarket notification under § 510(k) of the FDCA). (**Exhibit H**, Aff. of J. O'Donnell, 3:10-16.) Other products in the FreshLook® product line are intended for extended wear. (**Exhibit H**, Aff. of J. O'Donnell, 3:17-18.) These extended wear lenses are products classified as Class III medical devices requiring premarket approval under § 515 of the FDCA. *See See* 21 C.F.R. § 886.592(b)(2) (classifying extended wear lenses as Class III); *see also* 21 U.S.C. § 513(a)(1)(C) (requiring premarket approval under § 515 of the FDCA). (**Exhibit H**, Aff. of J. O'Donnell, 3:18-23.)

8. Whether containing products classified as Class II or Class III medical devices, each distinct FreshLook® product line contains as many as 200 distinct products. (**Exhibit H**, Aff. of J. O'Donnell, 4:1-2.) For example, the FreshLook® Colors™ product line features lenses available in four colors—i.e., blue, green, hazel, and violet—for each of the fifty-seven correctional powers offered (4 colors × 57 powers = 228 distinct products). (**Exhibit H**, Aff. of J. O'Donnell, 4:2-5.)

9. Thus, even though the Petition describes the "subject product" as a "Fresh Look" lens,

that description applies to well over a thousand distinct products bearing the FreshLook® mark. (**Exhibit H**, Aff. of J. O'Donnell, 4:5-8.) Thus also, when CIBA was served with the Petition on June 16, 2010, the Plaintiffs description of the "subject product" as a "Fresh Look" was not sufficient to provide any person notice as to whether the Plaintiffs allegations were referring to a Class II daily wear only product or a Class III extended wear product. (**Exhibit H**, Aff. of J. O'Donnell, 3:10-23.)

10. Although the Petition was not sufficient to provide such notice, on September 1, 2010, CIBA's counsel received a fax from Plaintiffs' counsel containing discovery requests ("*Plaintiffs' Discovery Requests*") that defined the "subject product" as "'FreshLook Colors' contact lenses." *See* **Exhibit I-1**, Pl.'s Discovery Requests, p. 4 ¶ a. One of CIBA's product lines bearing the FreshLook® mark is the FreshLook® Colors™ product line, which contains more than 200 distinct products. (**Exhibit H**, Aff. of J. O'Donnell, 4:2.)

11. Three business days after receiving Plaintiffs' Discovery Requests, CIBA's counsel requested Plaintiffs to provide more information necessary to identify which of the more than 200 products bearing the FreshLook® Colors™ marks was being referred to as the "subject product." (**Exhibit I-2**, Letter of Sept. 7, 2010.)

12. The next morning, Plaintiffs' counsel responded that "the subject lenses were marketed under the name 'Freshlook Colors' with no corrective power (cosmetic only) . . . the color is called 'hazel'." (**Exhibit I-3**, Email of Sept. 8, 2010.)

13. Two of the products in the FreshLook® Colors™ product line are hazel colored and feature no corrective power. One of the products is identified with the Universal Product Code ("*UPC*") number 730775473869, which is distributed in a package of six. (**Exhibit H**, Aff. of J. O'Donnell, 4:21-23.) The other product is identified with the UPC number 730778528948, which is a package of six demo lenses. (**Exhibit H**, Aff. of J. O'Donnell, 5:1-2.) The only difference between the products packaged under these different UPCs is that the demo products actually have the letters "DEMO" printed on the lenses themselves to indicate that the lenses are

for demonstration purposes and should not be sold. (**Exhibit H**, Aff. of J. O'Donnell, 5:2-5.) Despite this difference, all FreshLook® Colors™ hazel noncorrective lenses are indicated for extended wear, and they were approved by the Food and Drug Administration's ("*FDA*") premarket approval ("*PMA*") number P830037, as required for Class III medical devices. (**Exhibit H**, Aff. of J. O'Donnell, 5:6-13.)

14. Because Plaintiffs have identified the subject product as the FreshLook® Colors™ hazel noncorrective lens, Plaintiffs have revealed that product referenced in their Petition is a Class III medical device approved by the FDA's PMA number P830037. Because their claims regard a Class III medical device approved by the FDA's PMA, as explained below, Plaintiffs are completely preempted by the FDCA and the Medical Device Amendments ("*MDA*") thereto. Because Plaintiffs' claims are completely preempted by Federal law, this case arises under laws of the United States and presents a federal question jurisdiction of this Court justifying its removal from state court.

IV. THE BASIS FOR REMOVAL IS PROPER.

15. "[D]istrict courts shall have original jurisdiction of all civil actions *arising under . . . laws of the United States*." 28 U.S.C. § 1331 (emphasis added). Plaintiffs' action arises under laws of the United States because the Petition alleges statutory and "common-law causes of action for negligence and strict liability . . . [that are] pre-empted by federal requirements specific to a medical device." *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 323-24 (2008). Specifically, postpetition communications from Plaintiffs have revealed that they have artfully pleaded a claim completely preempted by federal law. In particular, the communications reveal that the subject product made the basis of Plaintiffs strict liability and negligence claims is the FreshLook® Colors™ hazel noncorrective contact lens, a medical device regulated and approved by the FDA's PMA process authorized by MDA. Because CIBA complied with the PMA process in designing, marketing, and manufacturing the FreshLook® Colors™ hazel noncorrective contact lens, and because the Plaintiffs' state law claims impose requirements that

potentially conflict with PMA requirements, CIBA's compliance with PMA preempts Plaintiffs' state tort law claims brought with respect to FreshLook® Colors™ hazel noncorrective contact lens. *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *see also Reigel*, 552 U.S. at 330 (holding that state causes of action may not impose statutory or common-law obligations any different than those imposed by FDA regulations for PMA devices, and that such causes of action are limited to "providing a damages remedy for claims premised on a violation of FDA regulations.").

(A) THE SUBJECT PRODUCT IS THE FRESHLOOK® COLORS™ HAZEL NONCORRECTIVE CONTACT LENSE.

16. Plaintiffs allege in their petition that CIBA and Novartis are "strictly liable as the designer, manufacturer, and marketer of the subject product." *See supra* ¶ 5, The Petition defines "subject product" to mean "the 'Fresh Look' non-prescription color contact lenses . . . originally designed, manufacturer [sic], marketed, warranted, and sold by . . . Ciba." *See supra* ¶ 5, Although none of CIBA's products are named or marketed as "Fresh Look," CIBA has as many as twelve distinct product lines bearing the FreshLook® mark. *See supra* ¶ 7. Because CIBA has as many as twelve distinct product lines bearing the FreshLook® mark, the Petition's definition of "subject product" was not sufficient to identify which of the product lines bearing the FreshLook® mark the subject product was alleged to be the product line featuring the subject product. *See supra* ¶ 9.

17. Although the allegations in the Petition were not sufficient to identify the particular FreshLook® product alleged as the "subject product," Plaintiffs' Discovery Requests later defined the "subject product" as "'FreshLook Colors' contact lenses." *See supra* ¶ 10. Plaintiffs' counsel further clarified in an email that "the subject lenses were marketed under the name 'Freshlook Colors' with no corrective power (cosmetic only) . . . the color is called 'hazel'." *See supra* ¶ 12.

18. One of CIBA's product line bearing the FreshLook® mark is the FreshLook® Colors™

product line. *See supra* ¶ 10. Two of the products in the FreshLook® Colors™ product line are hazel colored and feature no corrective power. *See supra* ¶ 13. Therefore, Plaintiffs have identified that the subject product referenced in their Petition and made the basis of this suit is a FreshLook® Colors™ hazel noncorrective contact lens.

(B) CIBA COMPLIED WITH THE PREMARKET APPROVAL PROCESS IN DESIGNING, MARKETING, AND MANUFACTURING THE FRESHLOOK® COLORS™ HAZEL NONCORRECTIVE CONTACT LENS.

19. All FreshLook® Colors™ hazel noncorrective lenses are indicated for extended wear. *See supra* ¶ 13. As extended wear lenses, all FreshLook® Colors™ hazel noncorrective contact lenses are classified as Class III medical devices requiring PMA under § 515 of the FDCA. *See supra* ¶ 7. In fact, all FreshLook® Colors™ hazel noncorrective lenses were approved by the FDA's PMA number P830037. *See supra* ¶ 13.

(C) PLAINTIFFS STATE LAW CLAIMS IMPOSE REQUIREMENTS THAT POTENTIALLY CONFLICT WITH PMA APPROVAL OF THE FRESHLOOK® COLORS™ HAZEL NONCORRECTIVE CONTACT LENS.

20. The Supreme Court of the United States has recently held that state causes of action may not impose statutory or common-law obligations or requirements that are any different than those imposed by FDA regulations for PMA devices. *Reigel*, 552 U.S. at 323-30. Plaintiffs have alleged state law claims that conflict with the PMA approval of the FreshLook® Colors™ Hazel noncorrective contact lens. Specifically, Plaintiffs allege in the Petition that the lens "was defective in its manufacture, and/or defective in its design, and/or defective in the manner of its marketing, and there were thus resulting misrepresentations" of the lens. (*See* **Exhibit B**, pp. 23, *Petition*, pt. VII.) Plaintiffs allege that the lens's warning, labeling, and instructions was not sufficient to "fully inform the end user of the risks of the product, including the risks of contamination, weakening of the eye's natural resistance to infection, risk of blinding infections, or that corneal ulcers can develop rapidly and lead to loss of vision." (*See* **Exhibit B**, pp. 23, *Petition*, pt. VII.) Plaintiff also alleges that the lens's warnings, instructions, and packaging were not "appropriate" or "proper" to convey information regarding health risks, disinfection,

duration of wear, and the necessity of using the lens under an eye care professional's supervision. (*See* **Exhibit B**, pp. 23-25, *Petition*, pt. VII.) Plaintiffs also claim the lenses their packaging should have employed safer alternatives. (*See* **Exhibit B**, pp. 23, *Petition*, pt. VII.) Plaintiffs also recast these same allegations as negligence for "improper design of warnings and instruction." (*See* **Exhibit B**, pp. 26-32, *Petition*, pt. VII.)

21. But, as explained above, all FreshLook® Colors™ hazel noncorrective lenses were approved by the FDA's PMA number P830037. *See supra* ¶ 13. Because the design, manufacture, distribution, and marketing of all FreshLook® Colors™ hazel noncorrective lenses were approved by the FDA's PMA number P830037, and because Plaintiffs allege such approved design, manufacture, distribution, and marketing was improper, inadequate, defective, or deficient, Plaintiffs seek to impose Texas statutory or common-law obligations or requirements that are different than those imposed by FDA regulations for PMA devices. "Simply put, Texas tort liability . . . would constitute a requirement either different from, or in addition to, a requirement—the Class III PMA process—that the MDA has made applicable" to all FreshLook® Colors™ hazel noncorrective lenses. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1423-24 (5th Cir. 1993); *accord Martin*, 254 F.3d 573 (5th Cir. 2001).

(D) CIBA'S COMPLIANCE WITH PMA COMPLETELY PREEMPTS PLAINTIFFS' STATE TORT LAW CLAIMS BROUGHT WITH RESPECT TO FRESHLOOK® COLORS™ HAZEL NONCORRECTIVE CONTACT LENS; AND THUS, PLAINTIFFS' ACTION RAISES A FEDERAL QUESTION SUFFICIENT FOR REMOVAL.

22. "State requirements pertaining to the safety or effectiveness of a device, or to any other matter included in a requirement made applicable to the device by the MDA, are preempted whenever they are different from, or in addition to, any requirement imposed upon the device under the MDA." *Stamps*, 984 F.2d at 1423-24 (5th Cir. 1993); *accord Martin*, 254 F.3d 573 (5th Cir. 2001); *see also Reigel*, 552 U.S. at 323-30 (2008). Where a statute has completely preempted any state cause of action, it leaves room for only a federal claim, and is thus proper for removal. *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 63-64 (1987); *Caterpillar Inc. v.*

Williams, 482 U.S. 386, 391 n.4 (1987). Because the MDA imposes the exclusive requirements on all manufacture of Class III PMA devices, removal of actions asserting negligence and products liability claims against Class III devices subject to PMA is proper. *Stamps*, 984 F.2d at 1423 (5th Cir. 1993) (upholding removal); *accord Martin*, 254 F.3d 573 (5th Cir. 2001) (reaffirming the holding in *Stamps* as applied to Class III devices subject to PMA); *but see Scott v. Pfizer, Inc.*, 182 F.App'x 312 (5th Cir. 2006) (unpublished opinion not permitting removal, but which was decided before the Supreme Court of the United States recognized complete preemption of state claims imposing additional or different requirements on Class III PMA devices in *Reigel*, 552 U.S. at 323-30 (2008)).

23. Because state requirements pertaining to the safety or effectiveness of a device, or to any other matter included in a requirement made applicable to the device by the MDA, are preempted whenever they are different from, or in addition to, any requirement imposed upon the device under the MDA, any state claims regarding Class III PMA devices such as FreshLook® Colors™ hazel noncorrective contact lenses are completely preempted by the MDA's requirements; and thus, Plaintiffs have raised a claim arising under the laws of the United States—i.e., the FDCA and MDA. "Any civil action of which the district courts have original jurisdiction founded on a claim *arising under . . . laws of the United States* shall be removable without regard to the citizenship or residence of the parties." 28 U.S.C. § 1441(b)(emphasis added).

V. THIS NOTICE OF REMOVAL IS TIMELY.

24. This notice of removal is timely because it has been "filed within thirty days after receipt by the defendant . . . of a copy of . . . paper from which it may be first ascertained that the case is one which is or has become removable." 28 U.S.C. § 1446(b). Because the Petition referred to a FreshLook® product that could have been either a Class II or Class III device, CIBA could not ascertain that the Petition alleged removable completely preempted claims regarding a Class III PMA device until it received Plaintiffs' Discovery Requests, which identified the product as

FreshLook® Colors™ (all of which are Class III devices), on September 1, 2010. *See supra* ¶¶ 5 - 13. This notice of removal was filed on September 30, 2010, which is twenty-nine days after receipt of CIBA's receipt of Plaintiffs' Discovery Requests; and thus, it is timely.

VI. ALL NECESSARY DEFENDANTS JOIN REMOVAL

25. Because removal of this action is based upon the federal claims of violations to the FDCA and MDA that apply to the design, manufacture, marketing, and distribution of the subject product, and because Plaintiff has alleged these claims only against CIBA VISION CORPORATION and NOVARTIS PHARMACEUTICAL CORP., joinder and consent to removal is required only for CIBA VISION CORPORATION and NOVARTIS PHARMACEUTICAL CORP, who have both joined in this notice for removal.

VII. SATISFACTION OF NOTICE

26. Defendants will promptly file a copy of this notice of removal with the clerk of the state court where the suit has been pending.

VIII. JURY DEMAND

27. Plaintiffs demanded a trial by jury in the Petition. (*See* **Exhibit B**, p. 29, *Petition.*)

IX. CONDITIONAL MOTION FOR LEAVE TO AMEND

28. CIBA and Novartis file this notice of removal in good faith and in accordance with applicable statues, the Federal Rules of Civil Procedure, and the Local Rules of this Court.

29. Should the Court or any party identify or allege any defect or deficiency in this notice of removal, CIBA and Novartis respectfully request the Court to grant it leave to amend this notice of removal to cure any such defect.

X. MOTION TO COMPEL PLAINTIFFS REPLEAD PREEMPTED CLAIMS PROPERLY

30. Because Plaintiffs' Texas state claims are completely preempted by federal law, their claims should be repleaded as alleged violations of the FDCA or MDA; and thus, CIBA and

Novartis respectfully request this Court to compel Plaintiffs to replead their claims accordingly.

XI. CONCLUSION

31. Because Plaintiffs' claims are completely preempted by federal law, this case arises under the federal question jurisdiction of this Court; and thus, CIBA and Novartis respectfully requests this Court to recognize and uphold removal of the suit to the Corpus Christi Division of the United States District Court for the Southern District of Texas.

DATED: September 30, 2010.

/s/Judd M. Treeman

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